

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

SON, Min

19th Floor, City Air Tower 159-9, Samseong-dong, Gangnam-gu, Seoul 135-973 Republic of Korea

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year) **02 MARCH 2006 (02.03.2006)**

Applicant's or agent's file reference
PCTA9511-685

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/KR2005/003934

International filing date (day/month/year)

22 NOVEMBER 2005 (22.11.2005)

Priority date(day/month/year)

23 NOVEMBER 2004 (23.11.2004)

International Patent Classification (IPC) or both national classification and IPC

A61K 31/426(2006.01)i

Applicant

DONG WHA PHARMACEUTICAL. IND. CO., LTD. et al

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/KR



Korean Intellectual Property Office
920 Dunsan-dong, Seo-gu, Daejeon
302-701, Republic of Korea

Facsimile No. 82-42-472-7140

Date of completion of this opinion

02 MARCH 2006 (02.03.2006)

Authorized officer

LEE, Mi Jeong

Telephone No. 82-42-481-5601



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/KR2005/003934

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material
☐ on paper
☐ in electronic form
 - c. time of filing/furnishing
☐ contained in the international application as filed.
☐ filed together with the international application in electronic form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
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International application No.

PCT/KR2005/003934

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1 - 9	YES
	Claims		NO
Inventive step (IS)	Claims	1 - 9	YES
	Claims		NO
Industrial applicability (IA)	Claims	1 - 9	YES
	Claims		NO

2. Citations and explanations :

The following document is referred to in this report:

D1: WO 03/007947 A1 (30 Jan. 2003)

1. Novelty

Claims 1-9 of the present invention relate to an N-hydroxy-4-5-[4-(5-isopropyl-2-methyl-1,3-thiazol-4-yl)phenoxy]pentoxy benzamidine 2 methanesulfonic acid salt, a method of preparing the said compound and a pharmaceutical composition comprising the said compound.

Methanesulfonic acid is disclosed as one of the pharmaceutically acceptable salts of the said compound in D1.

Since D1 does not disclose 2 methanesulfonic acid salt of the said compound, the novelty of claims 1-9 can be acknowledged over D1[Article 33(2) PCT].

2. Inventive Step

Although methanesulfonic acid is disclosed as one of the pharmaceutically acceptable salts of the said compound in D1, 2 methanesulfonic acid salt of the said compound cannot be easily expected by a man skilled in the art. Furthermore, the 2 methanesulfonic acid salt of the said compound shows surprisingly higher solubility and bioavailability than 1 methanesulfonic acid salt of the said compound does.

Therefore, the inventive step of claims 1-9 can be acknowledged over D1[Article 33(3) PCT].

3. Industrial Applicability

The subject-matter of claims 1-9 appears to be industrially applicable [Article 33(4) PCT].

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Box No. IV Lack of unity of invention



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